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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,456	11/09/2001	Amir Toporoik	2786-0185P	3079

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,456	TOPOROIK ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-55* is/are pending in the application.

4a) Of the above claim(s) *33,34,36,42 and 45-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-32,35,37-41,43 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. Applicant's amendment filed on 8/1/01 is acknowledged.

Status of Claims

2. Claims 1-27 have been canceled.

New claims 28-55 have been added and are pending in the application.

Election/Restriction

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Group I, claims 28-32, 35, 37-40, 41, 43 and 44 are drawn to nucleic acid, vector, host cell and pharmaceutical composition comprising said nucleic acid,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group II, claims 33-34, 42 and 44 drawn to a polypeptide and a pharmaceutical composition comprising said polypeptide,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group III, claims 36 and 45, drawn to an antibody polypeptide and a pharmaceutical composition comprising said antibody,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group IV, Claims 46, 48 and 49 drawn to a method of treating disease using nucleic acid,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group V, claim 47,drawn to a method of treating disease using peptide,

Group VI, claim 50 drawn to a method of treating disease using antibody,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group VII, claims 51-53 drawn to a method for detecting chordin like homolog, CLH product using nucleic acid,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group VII, claim 54 drawn to a method for detecting CLH product using antibody,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

Group VIII, claim 55 drawn to a method for detecting CLH product using peptide,

Further restriction to one SEQ.ID.NO required (see paragraph # 5).

4. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special feature technical features for the following reasons:

The technical feature of linking groups appears to be that they are all related to nucleic acids, peptides, and antibodies and methods of using peptides, nucleic acids and antibodies. However, Accession Number AK007577, disclose fragments of nucleic acid SEQ.ID.NO: 8 or 20 nucleotides of an isolated nucleic acid, SEQ.ID.NO: 8 (see the attached sequence alignment of SEQ.ID.NO: 8 with the prior art nucleic acid). Therefore, the technical feature of linking groups I-VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking.

The special technical feature of Group I is considered to be polynucleotide, which is made up of nucleic acids.

The special technical feature of Group II is considered to be polypeptide which is made up of amino acids, that shares no common structure, property and function with Group I nucleic acid and do not share the same or a corresponding technical feature with
Group I and do not require each other for their practice.
The special technical feature of Group III considered to be antibody that shares no common structure, property and function with Inventions I-II since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.
The technical feature of linking Groups IV-VIII is considered to be methods utilizing products such as nucleic acid, amino acids and antibody. However, nucleic acid lacks a special technical feature as it does not define a contribution over the prior art (Acession Number AK007577) as discussed above and also share no common structure, property and function with other products, polypeptide and antibody so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups IV-VIII.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

DISTINCT INVENTIONS

5. For each group of inventions I-VIII above, restriction to one of the following SEQ.ID.NO is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-VIII and one of SEQ ID NO: 1 – 11 or 12-22.

Inventions SEQ ID NO: 1 - 11 and SEQ ID NOS 12-22 are not so linked as to under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The claimed peptides and nucleic acid molecules SEQ.ID.NOS: 1-11 and 12-22 share no common special technical feature because the peptides and nucleic acid molecules have no common structure (i.e., no common sequence), property and function.

SEQ.ID.NOS: 1-11 and 12-22 represent sequences that share no common structure as polypeptides and the polynucleotides encoding them are not linked by the same the same or a corresponding special technical feature as to form a single general inventive concept.

Therefore, where structural identity is required, such as for hybridization or expression of protein or binding of antibody, each sequence appears perform a different function in that peptides elicit an antibody response and nucleic acids encode peptides that specifically bind to an antibody. Further, Carninci et al disclose fragments or at least 20 nucleotides of an isolated nucleic acid, SEQ.ID.NO: 8 Acession Number AK007577 (see the attached sequence alignment). Therefore, the technical feature of linking SEQ.ID.NO: 1-11 and 12-22 does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art and hence unity of invention is lacking. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among peptide (SEQ.ID.NOS) and nucleic acids (SEQ.ID.NOS).

Applicant is required under Restriction is required under 35 U.S.C. 121 and 372 to elect a single disclosed SEQ.ID.NO from any group elected.

6. During a telephone conversation with Marc Weiner on 1/27/04 a provisional election was made to prosecute the invention of Group 1, claims 28-32, 35, 37-40, 41, 43 and 44, SEQ.ID.NO: 8. Affirmation of this election must be made by applicant in replying to this Office action.

Status of claims

7. Claims 28-55 are pending in the application.

Claims 28-32, 35, 37-40, 41, 43 and 44 drawn to nucleic acid are under prosecution with respect to SEQ.ID.NO: 8. Applicant is advised to restrict the claims to read on SEQ.ID.NO: 8 only.

8. Claims 33, 34, 36, 42, 45-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Priority

9. This application is a national stage entry of is a national stage entry of PCT/IL00/00736 Filed on 11/10/2000, which claims foreign priority under 35 U.S.C. 119(a)-(d) to ISRAEL 133767 filed on 12/28/1999 and ISRAEL 133767 filed on 11/10/1999. The examiner has carefully examined the priority documents in support of the claimed invention. However, none of the foreign priority documents show support for the polynucleotide sequence, SEQ.ID.NO: 8.

10. Therefore, the benefit of the filing date of foreign applications has not been granted for the instantly examined claims.

Applicants are requested to provide the serial number and specific page numbers of any foreign application to which priority is desired which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims which applicant considers to have been in possession and fully enabled of prior to 11/20/2000.

Information Disclosure Statement

11. Information Disclosure Statement filed on 8/21/01 is acknowledged and a signed copy is attached to this Office action.

Specification Informalities

12. This application is informal in the arrangement of the specification. Applicant attention is directed to MPEP 608.01(a). Claims shoud begin with "I claim" or "'We claim" or "What is claimed is". Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Sequence Rule Non-compliance

13. The specification at line 10 and 12 on page 51 recites nucleotide sequences that are longer than ten bases in length, yet are not identified, by SEQ ID NO as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. All SEQ 1D numbers recited in the specification and/or the claims must be included in the Sequence Listing. Note that branched sequences are specifically excluded from this definition.

14. Applicants must submit such a paper copy and an amendment directing its entry at the appropriate section of the specification by an amendment.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R1.821 -1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

Claim Rejections - 35 USC § 101

15. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

16 Claims 28-32, 35, 37-40, 41, 43 and 44 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility.

Claims are drawn to an isolated nucleic acid sequence selected from:

(i) the nucleic acid sequence depicted in SEQ ID NO: 8;

(ii) nucleic acid sequences having at least70% or 80% or 90% or 95% identity with the sequence of SEQ ID NO:8 (iii)fragments of (i) or (ii) of at least 20 nucleotides. Claims are also drawn to an isolated nucleic acid sequence complementary to said nucleic acid and an isolated nucleic acid sequence coding for the amino acid sequence of SEQ.ID.NO: 8, expression vector, suitable host and a host cell transfected by the expression vector, a pharmaceutical composition comprising a pharmaceutically acceptable carrier and, as an active ingredient, the expression vector containing said nucleic acid and a pharmaceutical composition comprising a pharmaceutically acceptable carrier as an active ingredient and the nucleic acid sequence complementary to said nucleic acid (examiner considers fragments or at least 20 nucleotides and nucleic acid sequences having at least70% or 80% or 90% or 95% identity as variants and will be referred to variants in the Office action).

When determining whether an applicant has described the utility of invention, one has to determine whether the applicant has described a well-established utility. If not, has the application made any assertion of utility and whether the asserted utility is a specific and credible utility. In the instant case, the applicant claims a polynucleotide, SEQ.ID.NO: 8 and other polynucleotide variants thereof. When the claims are interpreted in the light of the specification, the specification discloses that the invention relates to Chordin like homologs and polynucleotides that encode said polypeptides. However, the specification does not provide any disclosure as to how is the polynucleotide or encoding polypeptides or claimed variants

related to any known proteins. The specification on discloses that the claimed polynucleotide encodes a chordin like protein that is involved in a key developmental protein that dorsalizes early vertebrate embryonic tissue by binding to TGF-beta like bone morphogenic protein and sequestering in latent complexes. However, the specification does not provide any disclosure as to how the polypeptide encoded by the claimed polynucleotide is related in the development of any tissue and what are the regulatory molecules that are involved in the development of tissue. Further, the specification does not disclose the expression of the protein encoded by SEQ.ID.NO: 8 in any tissue of a given subject. The specification does not disclose as to how similar or different the functions of the claimed polynucleotide encoded polypeptide would have been from that of the chordin polypeptide disclosed in the specification. If the function of the polypeptide is not established, how can its utility be established or be specific? What criteria an artisan would have used to determine whether the function of claimed polynucleotide encoded polypeptide are similar or different to that of the polypeptides disclosed in the specification? In light of the issue of function of the claimed polynucleotides, question also arises what will be the utility of vectors, host cells, and membranes that comprise the claimed polynucleotide? Logically, one would ask if an artisan did not know the function of a polynucleotide sequence, how would the artisan have known the consequence of the expression or inhibition of expression of such a polynucleotide sequence. Additionally, how would an artisan treat a disease for which the etiology or symptoms are not known or it is not known what disease would have been cured by the polynucleotide or its encoded polypeptide. Likewise how would an artisan have screened for compounds that affect the function of a polypeptide if the artisan had not known the function of the polypeptide?

Claims 28-32, 35, 37-40, 41, 43 and 44 in the currently written form, would encompass all the polynucleotide variants from all the living organisms that would have encodes a protein that

would have had at least 10% or more sequence identity with SEQ. ID NO: 8. However, the specification does not provide any description what these sequences would have been that would have encoded all these protein variants form all the living organisms, or how different or similar they would have been from SEQ. ID NO: 8. It is, therefore concluded that because the function of the SEQ. ID NO: 8 is not disclosed, the credibility of the asserted utilities for the claims 28-32, 35, 37-40, 41, 43 and 44 cannot be assessed.

In the event that the rejection under *35 USC 101* might be overcome, the following grounds of rejection would still apply. Claims 28-32, 35, 37-40, 41, 43 and 44 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 28-32, 35, 37-40, 41, 43 and 44 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the revised guidelines on written description available at www.uspto.gov (O.G. published January 30, 2001). This is a written description rejection.

The claims are discussed supra in Paragraph # 16.

The specification only describes a polynucleotide sequence of SEQ ID NO: 8. The specification describes as part of the invention an isolated polynucleotide SEQ ID NO: 8 and encoding the polypeptide SEQ ID NO: 19 is described as Chordin like homolog protein (CLH). However, broadly claimed nucleic acid sequences having at least 70% or 80% or 90% or 95% identity with the sequence of SEQ ID NO: 8 or fragments of polynucleotide SEQ ID NO: 8 or at least 20 nucleotides having at least 70% or 80% or 90% or 95% identity with the sequence of SEQ ID NO: 8. The examiner considers these as variants and will be addressed as variants in the Office action) are not set forth in this specification. Applicants also broadly describe the invention as embracing any substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides by use of language in which a specified percent of amino acids can be changed. As depending from these are the vectors, host cells, vaccines, diagnostics and methods of producing the polypeptide. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116).

The specification only discloses a polynucleotide sequence SEQ ID NO: 8, which correspond to the encoding polypeptide SEQ ID N0 19. Thus, an isolated polynucleotide sequence consisting of SEQ ID NO: 8 and an isolated polynucleotide that encodes the polypeptide meet the written description provision of 35 U.S.C. 112, first paragraph.

As noted in the Guidelines at Section I.A (2). The Written Description Guidelines state:

There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicant's invention as disclosed. The protein is uncharacterized by this specification and is asserted to belong to chordin like homolog. However, the protein has no specific biological properties dictated by the structure of the protein and the corresponding polynucleotide sequence. There must be some nexus between the structure of a polynucleotide sequence and function of the encoded protein. The specification fails to teach the function of the protein that is encoded by nucleotide, SEQ.ID.NO: 8 or relevant identifying characteristics of polynucleotide fragments or encoding polypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide consisting of SEQ ID NO: 8 and an isolated polynucleotide encoding the amino acid sequence SEQ ID NO: 19, fragments thereof and associated, vectors, fusion proteins etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure and function of the claimed polynucleotide or fragments/variants. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chugai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Thus, the specification fails to teach the function of the polynucleotide sequence and fragments/ variants of SEQ.ID.NO: 8, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed.

19. Claims 28-32, 35, 37-40, 41, 43 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To decide whether a specification is enabling, it is to be determined whether the specification discloses sufficient guidelines for successful making and using of the claimed invention without undue experimentation and whether sufficient examples have been provided. As described above (in written description rejection), the specification fails to describe sufficient guidelines for a skilled artist to have practiced the invention as claimed without undue experimentation because the specification does not provide sufficient guidance for making and using the fragments/variants of polynucleotide, SEQ.ID.NO: 8.

Claim Objections

20. Claim 35 is objected to because of the following informalities: Claim 35 is an improper dependent claim as it recites non-elected claim 34. Appropriate correction is required.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

21. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 28-32, 35, 37-40, 41, 43 and 44 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention,

Claim 28 is vague and indefinite in the recitation 'fragment' because it is unclear what is encompassed in this recitation. What constitutes a ` fragment', and how much of the protein's original structure has to be retained such that the resulting protein can be considered as a` fragment', is not clear. The metes and bounds of the structure encompassed in the limitation ` fragment ' is indeterminate.

Claim Rejections - 35 USC 102

22. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

23. Claims 28-32, 35, 37-40, 41, 43 and 44 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Accession number AK007577.

The claims are discussed supra in paragraph # 16

The transitional limitation "comprises" similar to the limitations, such as, "has", "includes," "contains," or "characterized by," represents open-ended claim language and therefore does not exclude additional, unrecited elements. See M.P.E.P 2111.03 [R-1]. See *Molecular Research Corp. v. CBS, Inc., 793 F2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448,*

450 (Bd. App.1948) ("comprising" leaves "the claim open. for the inclusion of unspecified ingredients even in major amounts". On the other hand, the limitation "consisting of represents closed claim language and excludes any element, step, or ingredient not specified in the claim. In *re Gray, 53 F. 2d 520, Il USPQ 255 (CCPA 1931); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948).*

Accession Number AK007577, disclose fragments of nucleic acid, SEQ.ID.NO: 8 including 20 nucleotides of an isolated nucleic acid, SEQ.ID.NO: 8 (claim 28, see the attached sequence alignment of SEQ.ID.NO: 8 with the prior art nucleic acid). Accession Number AK007577 anticipated the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's claimed isolated polynucleotide with the isolated polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

24. Claims 28-32, 35, 37-40, 41, 43 and 44 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Tang et al U.S.Patent 6,569, 662

Tang et al U.S.Patent 6,569, 662, disclose fragments of nucleic acid, SEQ.ID.NO: 8 including 20 nucleotides of an isolated nucleic acid, SEQ.ID.NO: 8 (claim 28, see the attached sequence alignment of SEQ.ID.NO: 8 with the prior art nucleic acid).
Tang et al anticipated the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's claimed isolated polynucleotide with the isolated polynucleotide of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product

of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Remarks

25. No claims are allowed. Claims 28-32, 35, 37-40, 41, 43 and 44 stand rejected.

Conclusion

26. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

3/15/04

MARK NAVARRO
PRIMARY EXAMINER